

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group Art Unit: 1647

Applicant: Jong Y. Lee

Serial No.: 09/016,159 Examiner: Fozia M. Hamud

Filed: January 30, 1998 Docket No.: 106.001US2

Title: PURIFIED HUMAN ERYTHROPOIETIN PROTEIN FRAGMENT

AND ANTIBODIES DERIVED THEREFROM

## **DECLARATION UNDER 37 C.F.R. § 1.132**

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

- I, Jong Y. Lee, declare and say as follows:
- 1. I am the inventor of the subject matter claimed in the above-identified U.S. Patent Application.
- 2. I have reviewed the Office Action mailed June 10, 2005 in relation to the above-identified patent application, and I make this declaration in support of the patentability of the claims of the patent application.
- 3. I hold a Ph.D. in Pathology and Epidemiology from the University of Minnesota. I am the author of numerous refereed publications in scientific journals.
- 4. The originally filed sequence listing in this patent application included a sequence (originally filed SEQ ID NO:4) for the cDNA and protein of the human erythropoietin (Epo) receptor and referenced the sequence listed as from Winkelmann, J.C. et al. (*Blood* 76:24-30 (1990)). The sequence provided was actually the sequence for the Epo receptor reported in Jones et al. (*Blood* 76:31-35 (1990)), which differs from the Winkelmann et al. sequence at 4 amino acid residues.
- 5. The disclosure of the Jones et al. sequence instead of the Winkelmann et al. sequence was an error by my patent attorney that I did not catch because the two sequences are nearly identical.
- 6. In my production of the erythropoietin binding protein (Epo-bp) as a soluble fragment of the erythropoietin receptor protein, which is described in the Examples of the

present application, I amplified the extracellular domain of the Epo-receptor by PCR from a full-length human Epo-receptor cDNA LAP37 with the sequence reported in Winkelmann et al. Thus, the Epo-bp that I produced has the sequence of residues 25 to 250 of the Winkelmann et al. sequence, not the Jones et al. sequence.

- 7. The Jones et al. sequence and the Winkelmann et al. sequence are presumably different isoforms of the Epo receptor present in the human population. I have no data, and I am aware of no data from others, suggesting that the two sequences function differently. Thus, to my knowledge both sequences function equally well as receptors in vivo in humans. More to the point for this invention, I believe that a protein fragment consisting of residues 25 to 250 of either the Winkelmann et al. sequence or the Jones et al. sequence would function equally well as soluble Epo binding proteins as is described in the present patent application. I have no reason to believe that one sequence would function any better than the other.
- 8. All statements made herein of my own knowledge are true, and all statements made on information and belief are believed to be true. Furthermore, these statements are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code, and with knowledge that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: 8/26/05 By: Jong Y. Lee